

# **EXHIBIT 235**

## **SUMMARY OF FDA INSPECTIONAL HISTORY OF AMIDE PHARMACEUTICAL, INC.**

### **MARCH 23, 1992**

Amide signed a Consent Decree with the FDA.

### **EI DECEMBER 12, 1992**

This December 12, 1992 to January 27, 1993 inspection was the first inspection conducted by the FDA after Amide entered into Consent Decree. An FD-483 was issued following conclusion of the inspection. A company response to the findings was submitted on January 27, 1993. In that response, Amide stated that it had investigated the problem areas, revised procedures, documented processes, and updated protocols accordingly. The District Office concluded that a re-inspection should be conducted to ascertain if Amide's commitments were being adhered to before the firm would be permitted to resume shipping their products.

### **EI MARCH 9, 1993**

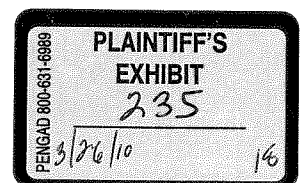
This re-inspection from March 9 to 17, 1993 resulted in a FD-483 being issued following the conclusion of the inspection. All the issues were addressed and as a result, we were permitted to freely manufacture and distribute all oral dosage form drugs that were dry blended. The one significant issue remaining from the inspection, drying oven qualification, was subsequently addressed and on May 7, 1993 the District gave us permission to proceed with those products using a wet granulation procedure.

### **EI MARCH 16, 1994**

The inspection of March 16, 1994 to April 1994 was conducted to determine if the firm was operating in compliance with the terms of the Consent Decree and cGMP's. An FD-483 was issued at the conclusion of the inspection. Through a written response to the FD-483, Amide was able to demonstrate to the District office that, indeed, the process validation studies for these products had been completed prior to shipment of the products. No adverse comments to our FD-483 response were received from the District.

### **EI FEBRUARY 14, 1995**

This pre-approval inspection for Digoxin Tablets Certification was conducted during eleven days between February 14 and March 16, 1995. Only one FD-483 observation was made at the conclusion of the inspection. A company response to the observation was submitted and the product was recommended for certification.



**EI MAY 2, 1995**

A pre-approval inspection of oral dosage form prescription drugs was conducted on this date. No FD-483 was issued. No adverse comments or observations were made concerning the products and the products were recommended for approval.

**JUNE 8, 1995**

FDA issued Batch certification to Amide, allowing Amide to initiate marketing of Digoxin Tablets (Generic to Lanoxin Tablets by [REDACTED]).

**JULY 20, 1995**

FDA exempted Amide from the requirement for Digoxin Batch Certification. Based on the letter, Amide was not required to send each batch to FDA for batch certification. Amide could manufacture and market the product as needed.

**SEPTEMBER 29, 1995**

The FDA approved ANDA for [REDACTED]  
[REDACTED]. This was our first ANDA after the signing of consent decree.

**EI NOVEMBER 9, 1995**

FDA conducted an inspection. No FD-483 was issued and the file was closed.

**EI APRIL 23, 1996**

The FDA conducted another pre-approval inspection on this date. An FD-483 was issued. Amide took the necessary actions, revised its SOPs, and submitted a timely response to the FD-483. FDA recommended approval of the product.

**JULY 12, 1996**

Amide requested FDA for the removal of Consent Decree based on its previous inspections.

**EI OCTOBER 25, 1996**

This inspection was conducted as the result of our initial request that the requirements of the Consent Decree be terminated. A FD-483 was issued as a result of the inspection. Amide responded to the FD-483 and no adverse comments to our FD-483 response were received from the District. However the district felt that the consent decree should not be removed at this time.

**EI JANUARY 10, 1997**

This inspection was a pre-approval inspection for (oral dosage form prescription drugs). No FD-483 was issued.

**EI JANUARY 22, 1997**

The FDA conducted an inspection. No FD-483 was issued.

**FEBRUARY 28, 1997**

Amide received approval of its first AB rated ANDA for [REDACTED]  
[REDACTED]

**MARCH 7, 1997**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**MAY 8, 1997**

Amide received supplemental approval for its ANDA [REDACTED]  
[REDACTED]

**EI MAY 14, 1997**

Another pre-approval inspection was held on this date. No FD-483 was issued. The EIR stated that the inspection covered a review of documentation pertaining to several prescription drug products. The review included but was not limited to product development reports, validation protocols, master batch records, executed batch records and associated raw data. The EIR states: "The inspection did not reveal any cGMP deficiencies".

**MAY 30, 1997**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**JUNE 18, 1997**

Amide received ANDA approval for [REDACTED]. This is the first ANDA in FDA's history to be approved in one cycle (approximately 6 months).

**JUNE 19, 1997**

Amide received ANDA approval for [REDACTED]. This ANDA was also approved in one cycle (approximately 6 months).

**JULY 25, 1997**

Amide requested that the FDA remove the Consent Decree based on its previous inspections.

**EI NOVEMBER 4, 1997**

This was a cGMP inspection conducted as a follow-up to Amide's second request of July 25, 1997 to be removed from the terms of the Consent Decree. An FD-483 was issued at the completion of the inspection. A company response to the FD-483 was submitted and reviewed by the District office. After much discussion between the District office and Amide representatives, Amide's response was deemed to be adequate and it was decided that a follow-up inspection would be made to confirm Amide's actions.

**DECEMBER 10, 1997**

Amide received approval for its ANDA for [REDACTED]

**EI JANUARY 30, 1998**

At the conclusion of this inspection for sample collection, the FDA did not issue an FD-483.

**EI APRIL 2, 1998**

This inspection was a pre-approval inspection covering three ANDA products. An FD-483 was issued containing only one observation. After submitting written response to the District office, Amide obtained approvable status for all the products.

**EI OCTOBER 28, 1998**

This FDA inspection was a pre-approval inspection (for oral dosage form prescription drugs). No FD-483 was issued.

**EI NOVEMBER 16, 1998**

The FDA conducted a routine inspection and no FD-483 was issued.

**EI DECEMBER 2, 1998**

The latest cGMP inspection was concluded on January 8, 1999. An FD-483 was issued. Amide revised its procedures, retrained employees, and made a timely response to the FD-483 without adverse comment on the part of the District office. At the conclusion of this inspection, FDA recommended removal of Consent Decree. Amide followed through on the FDA's recommendation, but unfortunately upon further review by FDA, they decided not to remove the Consent Decree.

**DECEMBER 29, 1998**

Amide received approval for its ANDA for [REDACTED]  
[REDACTED]

**DECEMBER 30, 1998**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI MARCH 2, 1999**

The FDA conducted a routine inspection and no FD-483 was issued.

**MARCH 15, 1999**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**MAY 26, 1999**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**MAY 28, 1999**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI SEPTEMBER 17, 1999**

This was a follow up inspection to review the flood damage caused by Tropical Storm Floyd. No FD-483 was issued at the conclusion of the inspection.

**OCTOBER 22, 1999**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI NOVEMBER 8, 1999**

This inspection was a pre-approval inspection for our pending ANDA products. An FD-483 was issued at the conclusion of the inspection. After submitting its written response to the District office, Amide obtained approvable status for all the products.

**DECEMBER 23, 1999**

Amide received ANDA approval for Digoxin Tablets, USP 0.125 mg and 0.25 mg.

**FEBRUARY 28, 2000**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**MARCH 14, 2000**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**MAY 23, 2000**

This inspection was a pre-approval inspection covering three ANDA products. A FD-483 was issued at the conclusion of the inspection. After submitting our written response to the District office, obtained approvable status for all the products

**JULY 26, 2000**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**DECEMBER 1, 2000**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI APRIL, 2001**

This inspection was a pre-approval inspection. No FD-483 was issued at the conclusion of the inspection.

**JULY 11, 2001**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI NOVEMBER 29, 2001**

This inspection was a general cGMP inspection and a pre-approval inspection. A one point FD-483 was issued at the conclusion of the inspection. After submitting our written response to the District office, obtained approvable status for all the products.

**MAY 9, 2002**

Amide received ANDA approval for [REDACTED]  
[REDACTED]



**JUNE 10, 2002**

Amide was formally released from the terms of the consent decree.

**AUGUST 2, 2002**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI NOVEMBER 13, 2002**

This inspection was a follow-up to the fire in room 123 on 8/19/2002. . No FD-483 was issued at the conclusion of the inspection.

**NOVEMBER 14, 2002**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**JANUARY 14, 2003**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**JANUARY 14, 2003**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**JANUARY 22, 2003**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI MARCH, 2003**

This inspection was a general cGMP inspection and a pre-approval inspection. A two point FD-483 was issued at the conclusion of the inspection. After submitting our written response to the District office, obtained approvable status for all the products.

**EI APRIL , 2003**

This inspection was a general cGMP inspection for the approval of our new facility at 4 Taft Road and a pre-approval inspection. A one point FD-483 was issued at the conclusion of the inspection. After submitting our written response to the District office, obtained approvable status for all the products.

**JUNE 25, 2003**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**AUGUST 20, 2003**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI AUGUST 21, 2003**

This inspection was a pre-approval inspection. A two point FD-483 was issued at the conclusion of the inspection. After submitting our written response to the District office, ANDA was deemed approvable by the District Office. Amide is awaiting approval by the center.

**OCTOBER 20, 2003**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**EI NOVEMBER 26, 2003**

This inspection was for collecting forensic samples for Amide product. No FD-483 was issued at the conclusion of the inspection.

**EI FEBRUARY 5, 2004**

This inspection was for collecting forensic samples for Amide product. No FD-483 was issued at the conclusion of the inspection.

**FEBRUARY 6, 2004**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**MARCH 31, 2004**

Amide received ANDA approval for [REDACTED]  
[REDACTED]

**REMARKS:**

Amide has responded in a timely and aggressive manner to each of the concerns expressed in the FDA's FD-483 observations. In fact, Amide's written responses documenting actions taken in response to the FD-483 observations in most cases have been accepted by the District without further comment or instruction. Furthermore, in the past nine years, the District has not suggested the recall of any of Amide's products, nor taken any action against Amide beyond issuing the FD-483's.